



FH

STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of

[REDACTED]
[REDACTED]
[REDACTED]

DECISION

MPA/167073

PRELIMINARY RECITALS

Pursuant to a petition filed July 03, 2015, under Wis. Stat. § 49.45(5), and Wis. Admin. Code § HA 3.03(1), to review a decision by the Division of Health Care Access and Accountability in regard to Medical Assistance, a hearing was held on August 20, 2015, at Phillips, Wisconsin. At the request of petitioner, the record was held open for petitioner to submit a new physician letter (in addition to Dr. [REDACTED]'s May 28, 2015 letter) to establish that petitioner's medical condition met the severity standards that the Division has set as a condition for Harvoni approval. The petitioner failed to submit any new physician letter or any other additional medical evidence to DHA.

The issue for determination is whether the Division correctly denied petitioner's prior authorization (PA) request for a non-preferred prescription drug, Harvoni.

There appeared at that time and place the following persons:

PARTIES IN INTEREST:

Petitioner:

[REDACTED]
[REDACTED]
[REDACTED]

||

Respondent:

Department of Health Services
1 West Wilson Street, Room 651
Madison, Wisconsin 53703

By: [REDACTED], R.Ph., pharmacy consultant
Division of Health Care Access and Accountability
1 West Wilson Street, Room 272
P.O. Box 309
Madison, WI 53707-0309

ADMINISTRATIVE LAW JUDGE:

Gary M. Wolkstein
Division of Hearings and Appeals

FINDINGS OF FACT

1. Petitioner is a 57 year old resident of Price County. He is certified for MA or BadgerCare Plus.
2. On May 14, 2015, a prior authorization request was submitted by [REDACTED] Pharmacy on the petitioner's behalf for Harvoni, a non-preferred prescription drug. The cost is listed as \$90,000 for 84 tablets, a 12 week supply of the medication. The Division issued written notice of denial of that request on May 18, 2015.
3. Harvoni is a drug known as a nucleotide analog inhibitor, which blocks a protein needed by the hepatitis C virus to replicate. Usually, it is a cure for the condition. The treatment duration for Harvoni is shorter than for older, cheaper drugs, such as Interferon.
4. The Division's basis for denial is that the petitioner's condition does not meet the severity standards that the Division has set as a condition for approval.
5. The petitioner, age 57, has diagnoses of chronic viral hepatitis C (Genotype 1a/b), anxiety, depression and insomnia. See Dr. [REDACTED]'s May 28, 2015 letter.
6. Currently, the petitioner's hepatitis C has not advanced to any of the following stages:
 - Compensated cirrhosis
 - Metavir score of F3 or greater or evidence bridging fibrosis
 - Hepatocellular carcinoma, if the s/he is on a liver transplant waiting list
 - Serious extra-hepatic manifestations of hepatitis C virus (HCV)

DISCUSSION

Federal MA rules do not require a state to cover prescription drugs; such coverage is at state option. 42 C.F.R. § 440.225. The Wisconsin MA program opted to pay for some prescription drugs. Wis. Admin. Code § DHS 107.10. Non-preferred prescription drugs must receive prior authorization as a condition of payment. *Id.*, 107.10(2)(d). In evaluating a prior authorization request, the program considers the authorization standards at § DHS 107.02(3)(e). Those standards include the requirements that the requested service be a medical necessity, appropriate, and cost effective, and that the existence of less expensive alternative services be considered. *Id.* The petitioner bears the burden of proving that these standards are met.

As an aid for consistent authorization request evaluation/approval for non-preferred, high-priced hepatitis C drugs, the Division's consultants prepared policy standards related to severity, which became effective in December 2014. Those published standards require that the patient's hepatitis C must have advanced to any of the following stages:

- Compensated cirrhosis
- Metavir score of F3 or greater or evidence bridging fibrosis
- Hepatocellular carcinoma, if the s/he is on a liver transplant waiting list
- Serious extra-hepatic manifestations of hepatitis C virus (HCV)

ForwardHealth Update, 2014-74 (November 2014) and *ForwardHealth Online Handbook*, at [https://www.forwardhealth.wi.gov/WIPortal/Online%20Handbooks/Display/tabid/152/Default.aspx?ia=1&p=1&sa=48&s=3&c=345&nt=Hepatitis C, Agents, Harvoni&adv=Y](https://www.forwardhealth.wi.gov/WIPortal/Online%20Handbooks/Display/tabid/152/Default.aspx?ia=1&p=1&sa=48&s=3&c=345&nt=Hepatitis%20C,%20Agents,%20Harvoni&adv=Y), Topic #17697, (viewed March 2015). The Wisconsin MA program does cover the less expensive prescription drug Interferon for treatment of less severe hepatitis C complications. *Id.*, *Preferred Drug List-Quick Reference*. I conclude that the above policy is reasonable.

There is no dispute that the petitioner's condition has not deteriorated to the levels identified in the above policy. He does not have cirrhosis of the liver, and his Metavir score is F2 based upon a liver biopsy performed on April 29, 2015. The petitioner is not on a liver transplant waiting list, and the prescriber did not identify serious extra-hepatic manifestations of the hepatitis C virus.

The petitioner indicated that he is not an IV drug user, which is consistent with his medical records. He is not currently on medication to treat his hepatitis C. He testified that he would prefer to be proactive regarding his health, and obtain this new medication to prevent future complications.

The petitioner has not established that he meets the program's authorization requirements for Harvoni. The Division's position is not unreasonable, and it is therefore sustained.

CONCLUSIONS OF LAW

1. The requested non-preferred prescription drug Harvoni is not a medical necessity, nor is it the most appropriate or cost effective method of treating the petitioner's condition at this time.
2. The Division correctly denied the prior authorization request for Harvoni.

THEREFORE, it is

ORDERED

The petition for review herein be and the same is hereby Dismissed.

REQUEST FOR A REHEARING

You may request a rehearing if you think this decision is based on a serious mistake in the facts or the law or if you have found new evidence that would change the decision. Your request must be **received within 20 days after the date of this decision**. Late requests cannot be granted.

Send your request for rehearing in writing to the Division of Hearings and Appeals, 5005 University Avenue, Suite 201, Madison, WI 53705-5400 **and** to those identified in this decision as "PARTIES IN INTEREST." Your rehearing request must explain what mistake the Administrative Law Judge made and why it is important or you must describe your new evidence and explain why you did not have it at your first hearing. If your request does not explain these things, it will be denied.

The process for requesting a rehearing may be found at Wis. Stat. § 227.49. A copy of the statutes may be found online or at your local library or courthouse.

APPEAL TO COURT

You may also appeal this decision to Circuit Court in the county where you live. Appeals must be filed with the Court **and** served either personally or by certified mail on the Secretary of the Department of Health Services, 1 West Wilson Street, Room 651, Madison, Wisconsin 53703, **and** on those identified in this decision as "PARTIES IN INTEREST" **no more than 30 days after the date of this decision** or 30 days after a denial of a timely rehearing (if you request one).

The process for Circuit Court Appeals may be found at Wis. Stat. §§ 227.52 and 227.53. A copy of the statutes may be found online or at your local library or courthouse.

Given under my hand at the City of Madison,
Wisconsin, this 23rd day of November, 2015

\sGary M. Wolkstein
Administrative Law Judge
Division of Hearings and Appeals



State of Wisconsin\DIVISION OF HEARINGS AND APPEALS

Brian Hayes, Administrator
Suite 201
5005 University Avenue
Madison, WI 53705-5400

Telephone: (608) 266-3096
FAX: (608) 264-9885
email: DHAmail@wisconsin.gov
Internet: <http://dha.state.wi.us>

The preceding decision was sent to the following parties on November 23, 2015.

Division of Health Care Access and Accountability